CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT (CRECD) IN MINORITY INSTITUTIONS

RELEASE DATE: February 12, 2003

RFA: RR-03-007

National Center for Research Resources (NCRR)
(http://www.ncrr.nih.gov/)
National Center on Minority Health and Health Disparities (NCMHD)
(http://ncmhd.nih.gov/)
National Eye Institute (NEI)
(http://www.nei.nih.gov/)
National Heart, Lung, and Blood Institute (NHLBI)
(http://www.nhlbi.nih.gov/index.htm)
National Institute on Aging (NIA)
(http://www.nih.gov/nia/)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov/)
National Institute on Drug Abuse (NIDA)
(http://www.nida.nih.gov/)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
(http://www.niddk.nih.gov/)

LETTER OF INTENT RECEIPT DATE: March 31, 2003

APPLICATION RECEIPT DATE: April 29, 2003

THIS RFA CONTAINS THE FOLLOWING INFORMATION:

PURPOSE OF THIS RFA

The National Center for Research Resources (NCRR) joins the National Center on Minority Health and Health Disparities (NCMHD), the National Eye Institute (NEI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute on Drug Abuse (NIDA), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in inviting minority institutions with professional schools offering doctoral degrees in one or more of the health care disciplines to apply for a Clinical Research Education and Career Development (CRECD) grant. Current CRECD awardee institutions may not apply for a second award.

CRECD awards are intended to support the development and implementation in minority institutions of curriculum-dependent programs to train selected doctoral and postdoctoral candidates in clinical research leading to a Master of Science in Clinical Research or Master of Public Health in a clinically relevant area. A successful program will result in an accredited master's degree program and will produce well-trained clinical researchers who can lead clinical research projects.

RESEARCH OBJECTIVES

As part of the Federal effort to eliminate racial and ethnic disparities in health, a need has been identified to expand the training of clinical researchers at minority institutions as one approach to fostering careers in clinical research addressing health disparities. Minority institutions conduct high quality programs for educating racial and ethnic minorities, and they represent a rich resource of talent with the appropriate cultural sensitivity and perspectives needed in clinical research. However, minority institutions have had difficulties developing and sustaining independent clinical research, and there is a paucity of racial and ethnic minority clinical researchers who are pursuing successful clinical research careers. There is a critical need for properly trained clinical researchers in certain health areas that disproportionately affect minority and underserved populations. Programs that include training specific to the unique knowledge, skills, and challenges needed to conduct clinical research in areas of interest to the participating NIH Institutes and Centers are strongly encouraged.

The scope of clinical research is broad. "NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research." [Instructions for the PHS 398 research grant application (rev. 5/01), Section III A., Definitions]

Excluded from this definition is research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Twelve ICs teamed to promote the first step in fostering the development of curricula in clinical research leading to a master's degree at minority institutions through RFA AR-00-009 for a one year planning grant in Fiscal Year 2001.

This Request for Applications (RFA) is a re-issuance of RFA AR-01-009, which was the second phase for development of curricula in clinical research leading to a master's degree at minority institutions, issued in Fiscal Year 2001. As was the case with RFA AR-01-009, it is not necessary for an institution to have held a planning grant to apply under this RFA.

PROGRAM: The award provides five years of support to a minority institution for a Clinical Research Education and Career Development (CRECD) program. The Principal Investigator leads a Curriculum Advisory Committee (CAC) to design, develop, implement and evaluate a curriculum for an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area. The award provides partial support for these activities and for external consultants and advisors. The award also provides partial salaries and stipends for doctoral and postdoctoral trainees and for other program-related research costs. The CRECD program must include curriculum-based, multi-disciplinary, didactic and collaborative training for clinical research as well as collaborative clinical research experiences for trainees to enhance clinical research skills.

The participating institution(s) must have well-established clinical research programs and faculty qualified in curriculum development and implementation, and in program evaluation, to serve as faculty for the program. The institution must demonstrate a commitment to provide sustained leadership and dedicated faculty time to the development and implementation of the program, and to develop productive, independent clinical investigators. The goal is to promote the development of well-trained clinical researchers who can lead clinical research studies addressing health disparities among the American people.

MECHANISM OF SUPPORT

This RFA will use the NIH educational project grant award mechanism (R25). As an applicant, you will be solely responsible for planning, directing, and executing the proposed program. The Principal Investigator and a co-director from each awardee institution will meet at least once a year with NIH staff to review program development. The total project period for an application submitted in response to this RFA may not exceed five years. This RFA is a one-time solicitation. The anticipated award date is September 30, 2003.

FUNDS AVAILABLE

A total budget for fiscal year 2003 of approximately $1.5 million will be committed to fund applications submitted in response to this RFA. An applicant may request a project period of five years and a budget for direct costs of up to $500,000 per year. It is anticipated that approximately three awards will be made in fiscal year 2003. This funding level is dependent upon the receipt of a sufficient number of meritorious applications and the availability of funds.

ALLOWABLE COSTS: No application may exceed $500,000 in direct costs. The Principal Investigator may request salary support for leadership, management, coordination, and evaluation of the CRECD program, in accordance with the percent effort commitment. This commitment should be at least a ten-percent effort. Faculty critical to the design, development, implementation and refinement of the specialized curriculum essential to the training and didactic needs of the CRECD program may be provided salary support in accordance with the percent effort of unique commitment. Salary support for Curriculum Advisory Committee members must be justified by their specific contributions to program development (see SPECIAL REQUIREMENTS). However, in general, it is assumed that many of these activities are within the normal scope expected of academic faculty and are supported by the applicant institution. The Principal Investigator and CRECD program faculty may derive additional compensation from other Federal sources or awards, provided the additional compensation does not exceed the maximum annual salary level for Federal employees (see WHERE TO SEND INQUIRIES) and their total percent effort on all awards does not exceed 100 percent. Moreover, compensation and expenses can be provided for external consultants and advisors.

Pre-doctoral appointees can be provided salaries/stipends of up to $20,000 per year plus fringe benefits commensurate with the institution's scale for persons of equivalent qualifications, experience, and rank. Up to two years of support can be provided for the master's degree. Salary and tuition may be applied only to those courses fulfilling requirements for the master's degree.

Postdoctoral/Faculty appointees can be provided salaries of up to $75,000 per year plus fringe benefits commensurate with the institution's full-time salary scale for persons of equivalent qualifications, experience, and rank. Postdoctoral appointees may include junior faculty (those within seven years of their first faculty appointment). Up to two years of support can be provided for the master's degree.

The institution may supplement the NIH contribution to an appointee's salary up to a level that is consistent with the institution's salary scale. Institutional supplementation of a salary must not require extra duties or responsibilities that would interfere with the purpose of the award.

Up to $20,000 in direct costs per year per trainee adjusted to the actual

percent effort can be provided for the following types of expenses: (a) research expenses, such as supplies, and technical personnel; (b) tuition, fees, and books related to career development; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time. These costs must be specifically documented for each individual candidate and must be specifically and directly related to the candidate's research activities.

Up to one full-time-equivalent (FTE) may be appointed to provide administrative support for this program. Funds may also be requested for the evaluation of the CRECD program.

Facilities and Administrative Costs: These costs, which were formerly called indirect costs, will be reimbursed at eight percent of modified total direct costs.

This R25 educational project grant, as administered by NIH, is not subject to the Streamlined Non-competing Application Process (SNAP). In general, this means that all reporting of budgetary information and CRECD program progress is provided in greater detail. This R25 grant is subject to Expanded Authorities except for changes in key personnel and the carryover of funds from one fiscal year to the next, which must be approved by Program and Grants Management staff.

ELIGIBLE INSTITUTIONS

Applications will only be accepted from Minority-Serving Institutions (MSIs) in the United States or in territories under U.S. jurisdiction. You may submit an application if your institution has the following characteristics:

o public or private non-Federal institution (such as a medical, dental, nursing, or pharmacy school) accredited to award master's and doctoral graduate degrees

o a comparable institution with graduate education programs; or a research institution that has on-going clinical research and clinical research training programs

o an institution serving students from racial and ethnic minority groups underrepresented in the biomedical sciences (e.g., African Americans, Hispanics, American Indians, Alaskan Natives, Native Hawaiians, and Pacific Islanders) comprising a majority (more than 50 percent) of the institution's enrollment.

The institution must demonstrate the commitment and capability to develop a core curriculum leading to an accredited Master of Science in Clinical Research degree or an accredited Master of Public Health degree in a clinically relevant area. An institution may submit only one application. Applicants are encouraged to develop consortia in common geographic locations to enhance the depth of their faculty and participant pools or to improve the quality of the educational experience. Institutions that already hold a CRECD grant may not apply for a second award.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed program is invited to work with her/his institution to develop an application for support. Individuals from underrepresented racial and ethnic groups, women, and persons with disabilities are encouraged to apply as Principal Investigators.

SPECIAL REQUIREMENTS

o The application must include a STATEMENT OF ELIGIBILITY of the applicant institution as a minority institution eligible for the CRECD Program.

o A specialized curriculum leading to an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area, not otherwise available at the institution or other participating institutions, must be developed and linked to the training goals and objectives of the CRECD program. The curriculum must include a clinical research component as a required part of the program.

o The Principal Investigator should possess the leadership and administrative capabilities required to lead the development of a clinical research curriculum. A minimum ten-percent effort is expected from the Principal Investigator.

o The Principal Investigator must assemble and chair a permanent multidisciplinary Curriculum Advisory Committee (CAC) representing all of the disciplines, departments, schools, institutions, etc. involved in this education and training program. The CAC will be responsible for the recruitment and selection of candidates for the CRECD program; the establishment and review of effectiveness of the curriculum; the approval of the education and training plans (e.g., curriculum, research experiences, mentors) for each candidate; interim monitoring and evaluation of each candidate's progress with recommendations for changes in the plan, if necessary, or termination of a candidate who is not making adequate progress; and monitoring and evaluation of the overall effectiveness of the CRECD program. The CAC will provide a summary report with each annual progress report that describes the Committee's actions and discusses progress of the CRECD program, including evaluation of areas of strengths and weaknesses. The use of external advisors or an external advisory committee is encouraged.

o All the mentors must be involved in clinical research or research methodologies clearly important to the clinical research focus and objectives of the proposed CRECD program.

o The applicant must describe the focus of its curriculum or the clinical training research program available to students and how it relates to one or more of the areas of interest to the participating NIH Institutes and Centers (e.g., health disparities, vision, ardiovascular disease, diabetes, aging, mental health/psychiatric disorders, drug abuse and addiction, etc.).

o The applicant must document the presence of a suitable group of doctorally-

qualified individuals to enroll in the proposed program. Doctorally-qualified individuals are those who have completed a doctoral degree or are in the final phase of completing a doctoral degree. All students must be United States citizens, non-citizen nationals or lawfully admitted permanent residents of the United States. The program can include as students junior faculty, post-doctoral trainees such as interns and residents, and doctoral candidates who seek to combine their clinical doctorate degree with a Master of Science in Clinical Research or a Master of Public Health in a clinically relevant area. Relevant clinical doctorate degrees include: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), Ph.D. with clinical responsibilities, or Pharm.D. Those individuals with a Ph.D. who want to become involved in clinical research also may participate.

o An evaluation plan must be provided for determining the performance of the processes and outcomes of the CRECD program. This plan must include the parameters and criteria that will be used to evaluate the CRECD program.

o The budget must contain funds for the CRECD Principal Investigator and a co-director to attend annual two-day meetings in Bethesda, Maryland. The purpose of these meetings will be for CRECD grantees to present their progress in the planning and implementation of their programs and to discuss common issues. NIH may invite selected extramural and intramural staff as consultants/experts on scientific and training issues.

o NIH staff reserve the authority to recommend reductions in budget, to withhold support, and to suspend and/or terminate the award if technical performance falls below acceptable standards for quality and timeliness.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. NCRR will be the lead in answering all inquiries. Inquiries may fall into three areas: programmatic, peer review, and financial or grants management issues:

o Direct your questions about programmatic issues to:

Dr. Shelia McClure
Division of Research Infrastructure
National Center for Research Resources
6705 Rockledge Drive, Suite 6030
Bethesda, MD 20892
Telephone: 301-435-0788
Fax: 301-480-3770
E-mail: mailto:mcclures@nccr.nih.gov

Contacts for Institutes and Centers participating in this RFA:

Dr. Tommy Broadwater
National Center on Minority Health and Health Disparities
6707 Democracy Blvd., Suite 800
Bethesda, MD 20892-5465
Telephone: 301-402-1366
Fax: 301-402-2517
E-mail: mailto:broadwatert@od.nih.gov

Dr. Chyren Hunter
Division of Extramural Research
National Eye Institute
Executive Plaza South, Suite 350
6120 Executive Blvd.
Bethesda, MD 20892-7164
Telephone: 301-451-2020
Fax: 301-402-0528
E-mail: mailto:clh@nei.nih.gov

Dr. Traci Mondoro
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 10182
Bethesda, MD 20892-7965
Telephone: 301-435-0052
Fax: 301-402-1056
E-mail: mailto:mondorot@nhlbi.nih.gov

Dr. Andre J. Premen
Geriatrics and Clinical Gerontology Program
National Institute on Aging
Gateway Building, Suite 480
7201 Wisconsin Avenue, MSC 9205
Bethesda, MD 20892-9205
Telephone: 301-496-6761
Fax: 301-402-1784
E-mail: mailto:premena@nia.nih.gov

Dr. Charisee Lamar
Program Director for Health Disparities and Women's Health Research
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Blvd., Suite 800
Bethesda, MD 20892-6500
Telephone: 301-594-5052
Fax: 301-480-4543
E-mail: mailto:lamarc@mail.nih.gov

Dr. Lula Beatty
Chief, Special Populations Office
National Institute of Drug Abuse
6001 Executive Blvd., MSC 9567
Bethesda, MD 20892-9567
Telephone: 301-443-0441
Fax: 301-480-8179
E-mail: mailto:lbeatty@nida.nih.gov

Dr. Lawrence Agodoa
Director of Minority Health Research Coordination
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd., Room 930
Bethesda, MD 20892-5458
Telephone: 301-594-9652
Fax: 301-480-4237
E-mail: mailto:agodoal@extra.niddk.nih.gov

o Direct your questions about peer review issues to:

Dr. Eric Brown
Scientific Review Administrator
National Center for Research Resources
6701 Rockledge Drive, Room 6018
Bethesda, MD 20892-7965
Telephone: 301-435-0815
Fax: 301-480-3660
E-mail: mailto:browne@ncrr.nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Irene Grissom
Office of Grants Management
National Center for Research Resources
6701 Rockledge Drive, Room 6086
Bethesda, MD 20892-7965
Telephone: 301-435-0844
Fax: 301-480-3777
E-mail: mailto:grissomi@ncrr.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Dr. Eric Brown
Scientific Review Administrator
National Center for Research Resources
6701 Rockledge Drive, Room 6018
Bethesda, MD 20892-7965
Telephone: 301-435-0815
Fax: 301-480-3660
E-mail: mailto:browne@ncrr.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/01). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.htmlin an interactive format. For further assistance contact GrantsInfo, telephone 301-435-0714, e-mail mailto:GrantsInfo@nih.gov

USING THE RFA LABEL: The RFA label available in the PHS 398 must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at http://grants.nih.gov/grants/funding/phs398/label-bk.pdf

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review
National Institutes Of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Dr. Eric Brown
Scientific Review Administrator
National Center for Research Resources
6701 Rockledge Drive, Room 6018
Bethesda, MD 20892-7965
Telephone: 301-435-0815
Fax: 301-480-3660
E-mail: mailto:browne@ncrr.nih.gov

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. Simultaneous submission of essentially identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

SUPPLEMENTAL INSTRUCTIONS: Applications for the CRECD award must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/01) and the modified instructions below, which take into account all of the special features and requirements of this grant.

o Face Page (page AA of form PHS 398): On Line 1 include the title that best represents the nature of your education and career development program. On line 2, provide the number and the title of this RFA.

o Description, Performance Site(s), Key Personnel (page BB of form PHS 398): Complete as directed in the form PHS 398 instruction package. Include the Principal Investigator, Curriculum Advisory Committee members, mentors and other faculty participating in the CRECD program. Please make sure that you include each individual's degree and departmental affiliation (or equivalent) and, if a consortia of institutions, institutional affiliation.

o In the Detailed Budget for the First Year (form DD) under Personnel, include the following individuals with percent effort, salary, and fringe benefits: (1) the Principal Investigator; (2) faculty being paid from the grant; (3) pre-doctoral candidates by name OR position (when position is not filled); and (4) postdoctoral/junior faculty candidates by name OR position (when position is not filled).

For Research and Development Costs, maintain a separation between pre-doctoral and postdoctoral candidates. For the budget categories other than salary, specifically identify the requested costs under each budget category (e.g., supplies, travel) for each trainee by name OR position (if the position is not filled), remembering that the total for each individual cannot exceed $20,000. Under travel, include funds for the Principal Investigator and one co-director to attend annual two-day meetings in Bethesda, Maryland.

o Biographical Sketches: Provide biographical sketches using the forms provided in the form PHS 398 package for the Principal Investigator, Curriculum Advisory Committee members, mentors, other participating faculty, and trainees (for those that are available).

o The application must include a STATEMENT OF ELIGIBILITY of the applicant institution as a minority institution eligible for the CRECD Program; and must document the presence of a suitable group of doctorally-qualified individuals to matriculate in the proposed program (see ELIGIBLE INSTITUTIONS).

o The Education and Career Development Plan (not to exceed 25 pages, excluding tables) must include:

(1) the background, purpose and objectives of the CRECD program;

(2) a description of the requirements that each candidate is expected to complete that will lead to either an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area;

(3) a description of the proposed core curriculum that includes an explanation of how the development and implementation of this curriculum is critically linked to the purpose and objectives of the CRECD program and to the research career development of individual candidates, and that explains how this curriculum is distinguished from other curricula within the existing educational infrastructure and framework of the pplicant/participating institution(s);

(4) a description of other didactic experiences utilizing any existing curricula within the institution(s);

(5) a description of the research activities and experiences that will be offered to the students by the mentors participating in the program;

(6) a description of the characteristics of candidates who will be selected for participation, recruiting strategies, the size of the candidate pool expected, and any other institutional programs that might compete for this pool (include strategies for addressing this competition);

(7) a description of individual candidate training plans that provide examples of individual plans to provide a unique education and career development experience for candidates, preparing them to design, implement, and participate in highly inter-disciplinary, collaborative clinical research (sample plans might address the needs of the combined degree doctoral student, a postdoctoral student who is an intern or resident, or a junior faculty member); and of plans for conducting the required review process for each candidate;

(8) a description of the research infrastructure; access to patient populations, community populations, etc.; and facilities that are available and accessible to this CRECD program; as well as a discussion of how an active research environment will be sustained to meet the needs and objectives of the CRECD program;

(9) a description of the qualifications and role of the Principal Investigator in providing leadership and coordination of the CRECD program (A minimum of ten-percent effort is required);

(10) a description of the qualifications of the faculty research mentors, including information on their experience in conducting clinical research;

(11) a description of how the Curriculum Advisory Committee (CAC) will function in providing oversight of the development, implementation, and evaluation, of recruitment strategies; recruitment and selection of candidates for the CRECD program; establishment, implementation, and evaluation of the core/specialized curriculum; approval of individual education and career development plans (e.g., curriculum, research/methodology experiences, mentors); interim monitoring and evaluation of each candidate's progress, including a determination of when a candidate has successfully completed the program, with recommendations for changes in the plan and, if necessary, termination of a candidate not making adequate progress; and monitoring of the overall effectiveness of the CRECD program; and

(12) a description of the information, time-line, and criteria to be used in evaluating the CRECD program.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review (CSR) and by NIH program staff for responsiveness and adherence to the eligibility criteria for this RFA. Incomplete and/or non-responsive applications WILL BE RETURNED to the applicant without further consideration.

Applications that are complete and responsive to this RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Office of Review of NCRR in accordance with standard NIH peer review procedures. As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
o Will receive a second level review by the NCRR National Advisory Research Resources Council.

REVIEW CRITERIA

All applications in response to this RFA will be evaluated for scientific and technical merit of the education career development plan using the criteria noted below.

Purpose and Objectives:

o clarity and importance of the CRECD program's purpose and objectives

o adequacy in meeting the NIH's intent of supporting education and career development programs that prepare candidates to participate as independent investigators in clinical research

Core Requirements:

o degree to which all of the core requirements combine to satisfy the training and career development objectives of the CRECD program

o quality of the process for evaluating each candidate's needs relative to the core requirements of the CRECD program

o adequacy of the subject matter and design of specialized curriculum, adequacy of the linkage of the specialized curriculum to the research training of the candidates, uniqueness of the specialized curriculum relative to other curricula available at the institution(s), and adequacy of the faculty responsible for the specialized curriculum

o strength and availability of other didactic experiences available for each candidate's education and career development

o adequacy of the breadth and depth of research experiences available to candidates to achieve their multidisciplinary training objectives

Research Base/Resources and Facilities/Mentors:

o adequacy of the research environment in the CRECD program to support the proposed education and career development

o adequacy of the available research infrastructure and patient populations to support the CRECD program

o quality of the mentors' research experience and likelihood of their success in training clinical scientists in the CRECD program

Program Leadership/Management:

o adequacy of the Principal Investigator's experience and qualifications to lead and coordinate the CRECD program

o recruitment (adequacy of the pool of candidates and the criteria for selecting high-quality candidates)

o appropriateness and experience of the CAC membership

o adequacy of the CAC's involvement as a quality control in selecting candidates for the CRECD program, and in establishing appropriate training plans for each candidate based on their individual needs and the CRECD program core requirements

o adequacy of plans for monitoring the progress of candidates and making mid-course corrections to improve the quality and effectiveness of each candidate's experiences, plans for evaluating a research thesis, and plans for terminating candidates for evident lack of performance

o adequacy of CAC plans for monitoring and evaluating the overall performance and effectiveness of the CRECD program

Individual Candidate Training Plans:

o quality and completeness of the sample training plans relative to the purpose and objectives and core requirements of the CRECD program

Evaluation Plan:

o adequacy of the criteria and process for evaluating the performance of the CRECD program

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: March 31, 2003
Application Receipt Date: April 29, 2003
Peer Review Date: June 2003
Council Review: September 2003
Earliest Anticipated Start Date: September 30, 2003

AWARD CRITERIA

Award criteria that will be used to make award decisions include: quality/scientific merit of the proposed CRECD program (as determined by peer review); availability of funds; and programmatic priorities.

REQUIRED FEDERAL CITATIONS:

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD:
Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htmand at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.htmlOnly research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov/). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no

obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93389, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of title III, Section 301 of the Public Health Service Act as amended, and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/nihgps_2001/and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.